Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte THORSTEN BLUME,
PETER ESPERLING, and
JOACHIM KUHNKE

Appeal No. 2002-1093
Application No. 09/288,691

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and SCHEINER, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 16 through 18. Claims 1, 2, and 6, which are the only other claims remaining in the application, stand allowed.

The Invention

The invention relates to a process for preparing 4,4-dimethyl-5α-cholesta-8,14,24-trien-3β-ol (FF-MAS). As stated in the specification, page 1, second paragraph, previous studies have shown that FF-MAS, isolated from human follicular

fluid, is an endogenous substance that regulates meiosis, to which advantageous hormonal effects are attributed. Accordingly, this substance is of importance for pharmaceutical applications, e.g., for promoting fertility.

At the time applicants' invention was made, a first synthesis of this natural substance was known in the art and described by Dolle et al. (J. Am. Chem. Soc., 1989, III: 278). In that synthesis, FF-MAS is obtained in 18 steps at great cost, starting from ergosterol (specification, paragraph bridging pages 1 and 2).

Another synthesis of FF-MAS, starting from dehydrocholesterol and carried out in 13 steps, was described by Schroepfer et al. (Bioorg. Med. Chem. Lett., 1997, 8: 233) (specification, page 2, first full paragraph).

Applicants have developed new processes for the synthesis of FF-MAS. As stated in the specification, page 2, last paragraph:

> By the two processes according to the invention, considerably fewer intermediate steps take place than within the known syntheses [sic] of Dolle et al. The number of purification steps is considerably lower, and no technically complex devices, such as an ozone generator with the facilities that are necessary for its operation, are required.

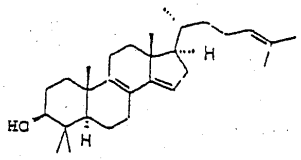
Applicants' "process variant 1" is described at length in the specification, pages 3 through 13; and illustrated in diagram 1 at page 11. Likewise, "process variant 2" is described in the specification, pages 13 and 14; and illustrated in diagram 2 at page 14. Additionally, "process variant 1" is the subject of example 2 (specification, pages 22 through 26); and "process variant 2" is the subject of example 1 (specification, pages 15 through 21).

This application contains allowed claims. Claim 1 recites a multi-step process for preparing FF-MAS, including all of the steps illustrated in diagram 1 (specification, page

11). By the same token, claim 2 recites a multi-step process for preparing FF-MAS, including all of the steps illustrated in diagram 2 (specification, page 14). The claims on appeal also recite a process for preparing FF-MAS. Unlike claims 1 and 2, however, the claims on appeal do not positively recite a series of steps. For example, claim 16 is a "comprising" type claim which positively recites a single step, viz., "isomerizing a compound of formula 6."

Claim 16, which is illustrative of the subject matter on appeal, reads as follows:

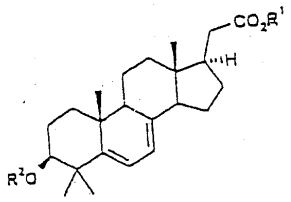
16. A process for the production of 4,4-dimethyl-5α-cholesta-8,14,24-trien-3β-ol of formula 1



(1)

comprising:

isomerizing a compound of formula 6



(6)

R^1 means hydrogen, branched or unbranched C_1-C_6 alkyl; phenyl; benzyl; ortho-, meta- or para-methylphenyl,

R^2 means hydrogen, an ester of an aliphatic or an aromatic carboxylic acid, an acetal protective group, or a silyl ether

Prior Art References

In rejecting claims 16 through 18, the examiner does not rely on any prior art references.

The Issue

The appealed claims do not stand rejected on prior art grounds; nor do they stand rejected for failing to comply with the written description, enablement, or best mode requirements of 35 U.S.C. § 112, first paragraph.

The question presented is whether the examiner erred in rejecting claims 16 through 18 under 35 U.S.C. § 112, second paragraph, for not particularly pointing out and distinctly claiming the subject matter which applicants regard as their invention.

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including all of the claims on appeal; (2) applicants' Appeal Brief (Paper No. 17) and the Reply Brief (Paper No. 19); (3) the Final Rejection mailed November 30, 2000 (Paper No. 10); and (4) the Examiner's Answer (Paper No. 18).

On consideration of the record, including the above-listed materials, we reverse the examiner's rejection under 35 U.S.C. § 112, second paragraph.

Discussion

As stated in Solomon v. Kimberly-Clark Corp., 216 F.3d 1372 , 1377, 55 USPQ2d 1279, 1282 (Fed. Cir. 2000):

> for a claim to comply with section 112, paragraph 2, it must satisfy two requirements: first, it must set forth what "the applicant regards as his invention," and second, it must do so with sufficient particularity and distinctness, i.e., the claim must be sufficiently "definite."

In the Final Rejection mailed November 30, 2000 (Paper No. 10), the examiner argues that claims 16 through 18 are not sufficiently definite and, therefore, do not comply with 35 U.S.C. § 112, second paragraph. According to the examiner, "[t]he claims are indefinite because they do not recite a complete process" (Paper No. 10, page 2). In section (10) of the Examiner's Answer (Paper No. 18), setting forth "Grounds of Rejection," the examiner adheres to the position that claims 16 through 18 are indefinite "because they do not recite a complete process for the production of the compound of formula 1." But the examiner does not explain why persons skilled in the art would not be reasonably apprised of the metes and bounds of claims 16 through 18. For example, if persons skilled in the art carry out a process for preparing FF-MAS, including the step of isomerizing a compound of formula (6), it would seem reasonably clear that such persons infringe the process recited in claim 16; otherwise, they do not. On this record, the examiner does not adequately state a prima facie case of indefiniteness of claims 16 through 18 but, instead, rests on a subjective belief that the appealed claims "do not recite a complete process." That is not enough to establish that applicants' claims fail to comply with 35 U.S.C. § 112, second paragraph.

In section (11) of the Examiner's Answer, entitled "Response to Argument," the examiner appears to "switch horses" and to argue that claims 16 through 18 do not set

forth what applicants regard as their invention. Again, however, the examiner does not rely on adequate reasons or evidence which would support her position but only on a subjective belief that applicants' claims are incomplete. Again, that is not enough to establish that claims 16 through 18 fail to comply with 35 U.S.C. § 112, second paragraph.

The examiner's decision rejecting claims 16 through 18 under 35 U.S.C. § 112, second paragraph, is reversed.

REVERSED

Sherman D. Winters Administrative Patent Judge	)
William F. Smith Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
Toni R. Scheiner Administrative Patent Judge	)

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